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EXAMINER	
ROYDS, LESLIE A	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,855	WOLTERING, EUGENE A.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-16* is/are pending in the application.

4a) Of the above claim(s) *15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-14* is/are rejected.

7)☒ Claim(s) *4 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08 April 05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-16 are presented for examination.

Acknowledgement is made of the present application as a National Stage (371) application of PCT Application No. PCT/IB03/04514, filed October 13, 2003, in addition to Applicant's claim for benefit of U.S. Provisional Patent Application No. 60/418,592, filed October 15, 2002.

Applicant's Information Disclosure Statement (IDS) filed April 8, 2005 (one page total) has been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449 (one page total), the Examiner has considered the cited references.

Requirement for Restriction/Election

Applicant's election of the invention of Group I (claims 2-9), directed to a method of treating a warm-blooded animal having hyperparathyroidism comprising administering a therapeutically effective amount of an epothilone derivative of formula (I) or a pharmaceutically acceptable salt thereof to a warm-blooded animal in need thereof, for examination on the merits, in the reply filed July 16, 2009, is acknowledged by the Examiner. Because Applicant did not distinctly and specifically point out the supposed errors in the requirement, the election has been treated as an election **without traverse** (MPEP §818.03(a)).

Applicant requests reconsideration of the restriction requirement because the causes of the hypercalcemia as recited in instant claim 10 (i.e., parathyroid adenoma, parathyroid hyperplasia, and parathyroid carcinoma) are each forms of hyperparathyroidism.

Applicant's request has been fully and carefully considered. Upon reconsideration of the claimed subject matter, the claims originally designated as Groups I (claims 2-9) and II (claims 10-14) will be herein rejoined for examination.

Therefore, for the reasons above and those made of record at p.2-6 of the previous Office Action

dated June 25, 2009, the requirement remains proper and is hereby made **FINAL**.

Claims 15-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being directed to non-elected subject matter, there being no allowable generic or linking claim.

The claims that are drawn to the elected invention and elected species are claims 2-14 and such claims are herein acted on the merits.

Objection to the Declaration

The declaration submitted with the papers filed October 18, 2005 is defective because the declaration contains non-initialed and/or non-dated handwritten alterations to the residence information provided for inventor Eugene Woltering. Please see 37 C.F.R. 1.52(c). A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by application number and filing date is required. See MPEP §§602.01 and 602.02.

Objection to the Claims

Claim 4 is objected to for reciting the "method according to claim 2 in which method an epothilone derivative", which is grammatically awkward. Applicant may wish to consider amending the claim to read ---method according to claim 2 ~~in which method~~ wherein an epothilone derivative--- in order to obviate the instant objection, but is reminded that the adoption of such a suggestion does not necessarily obviate any other objection and/or rejection set forth *infra*.

Claim 12 is objected to for reciting the "method according to claim 2 in which method an epothilone derivative", which is grammatically awkward. Applicant may wish to consider amending the claim to read ---method according to claim 10 ~~in which method~~ wherein an epothilone derivative--- in order to obviate the instant objection, but is reminded that the adoption of such a suggestion does not necessarily obviate any other objection and/or rejection set forth *infra*.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3, 6-11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the limitation "Z is O or a bond" as recited in instant claims 2 and 10 renders the claim indefinite because the structure of the claimed epothilone compound is not clearly set forth for the circumstance wherein Z is a bond. Specifically, it is unclear if, when Z is a bond, if Z is intended to form either a cyclopropyl ring or a cyclobutyl ring structure. In other words, the claims fail to clearly set forth whether Z simply bonds the carbon groups already present in the structure or if Z adds an additional bond to the structure (thus, forming a cyclobutyl ring). As a result, one of ordinary skill in the art at the time of the invention would not have been reasonably apprised of the scope of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 5 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, there is insufficient basis for the limitation "the preceding treatment" in line 3 of claims 5 or 13, since the preceding text of the claim or the claim from which it depends fails to set forth any reference to "a preceding treatment" *per se*.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112,

second paragraph, and are, thus, properly rejected.

Claims 6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, there is insufficient basis for the limitation “the hyperparathyroidism disease” in line 2 of claims 6 and 9, since the preceding text of the claim or the claim from which it depends fails to set forth any reference to "a hyperparathyroidism disease" *per se*.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, there is insufficient basis for the limitation “the parathyroid cancer disease” in line 2 of claim 8, since the preceding text of the claim or the claim from which it depends fails to set forth any reference to “a parathyroid cancer disease” *per se*.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, there is insufficient basis for the limitation “the disease” in line 2 of claim 14, since the preceding text of the claim or the claim from which it depends fails to set forth any reference to “a disease” *per se*.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112,

second paragraph, and is, thus, properly rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (U.S. Patent Application Publication No. 2002/0119202; Issued August 29, 2002, Filed August 9, 2001) in view of Altmann et al. ("Epothilones and Related Structures-A New Class of Microtubule Inhibitors with Potent In Vivo Antitumor Activity", *Biochimica et Biophysica Acta*, 1470 (2000):M79-M91) and Cecil's Textbook of Medicine (Twenty-First Edition, Vol.2; 2000; p.1402-1403).

Hunter et al. teaches anti-angiogenic compositions, as well as methods for utilizing such compositions for the treatment of cancer and other angiogenesis-dependent diseases, wherein the composition comprises (a) an anti-angiogenic factor and (b) a polymeric carrier (p.2, para.[0014]). Hunter et al. teaches that the anti-angiogenic factor that may be used include, *inter alia*, anti-invasive factor, retinoic acid and derivatives thereof, paclitaxel, suramin, etc. (p.7, para.[0100]), and further discloses that

the anti-angiogenic compositions may additionally comprise compounds in addition to the anti-angiogenic factor and polymeric carrier, such as, *inter alia*, one or more compounds that disrupt microtubule function, e.g., epothilone (p.9, para.[0114]). Hunter et al. teaches that the disclosed anti-angiogenic compositions may be employed in embolization therapy such that they are non-toxic, thrombogenic, easy to inject down vascular catheters, etc. (p.11, para.[0129]) for the treatment of benign tumors, including endocrine tumors, such as parathyroid adenomas (p.11, para.[0130]).

Note that, though Hunter et al. does not explicitly teach the treatment of recurrent or persistent parathyroid adenoma, the very teaching of "parathyroid adenoma" *per se* is understood to circumscribe both recurrent and persistent parathyroid adenoma, since recurrent or persistent adenoma provides for the two possible types of parathyroid adenoma that a subject suffering from said disease would exhibit (i.e., persistent, in the sense that it does not resolve, or recurrent, in that it resolves and returns). This genus of possible types of parathyroid adenoma is sufficiently limited in size so as to place each member of the genus within the possession of the public.

Hunter et al. fails to teach (1) the use of the particular epothilone compounds of the instant claims (claims 2 and 4), (2) the particular dosing schedule (claim 5) or (3) that the hyperparathyroidism is primary hyperparathyroidism (claim 9).

Altmann et al. teaches epothilone compounds, such as those described in Fig.1 (i.e., epothilone A and epothilone B, which correspond to Applicant's instantly claimed epothilone structure of formula (I) wherein R is hydrogen for epothilone A or R is methyl for epothilone B; A is oxygen and R' is methyl; p.M80, col.1), that function as microtubule inhibitors with the ability to inhibit the growth of multi-drug resistant human cancer cell lines (p.M89, cols.1-2).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ any one of the epothilone compounds (e.g., epothilone A or B) in the anti-angiogenic composition disclosed by Hunter et al. as effective for the treatment of benign tumors, such as parathyroid

adenoma, because Altmann et al. teaches that each of the disclosed epothilone compounds are one of a finite number of epothilone microtubule inhibitors known in the prior art at the time of the invention to predictably function as an anti-cancer agent. In other words, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ any one of the known anti-cancer epothilone microtubule inhibitors (which, as evidenced by Altmann et al., includes, *inter alia*, epothilone A or B) into the formulation of Hunter et al. for use in treating parathyroid adenoma with a reasonable expectation of success because (1) a person with ordinary skill in the art has good reason to pursue known options within his or her technical grasp (i.e., in the instant case, known anti-cancer epothilone microtubule inhibitor agents) and (2) Hunter et al. teaches the desirability of including such a microtubule inhibitor into the disclosed anti-angiogenic composition for the treatment of cancers.

Regarding the instantly claimed dosage regimen (i.e., administering the epothilone weekly in a dose that is between about 0.1-6 mg/m^2 for three weeks after an interval of one to six weeks after the preceding treatment; claim 5), the determination of the optimal dosage regimen would have been a matter well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination and, if so, the identify and mechanism of action of the other drug such that any interactive effects may be taken into account. Thus, the dosage regimen and/or manner of administration that would have actually be employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Cecil's Textbook of Medicine teaches that primary hyperparathyroidism is a disorder in which hypercalcemia is due to hypersecretion of parathyroid hormone and is caused by solitary adenomas in about 85% of cases (p.1402).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious that the parathyroid adenomas to be treated by the method and compositions disclosed by Hunter et al. were the cause of primary hyperparathyroidism in the subject because, as evidenced by Cecil's, the majority of cases of primary hyperparathyroidism are caused by parathyroid adenomas. Such a person would have had a reasonable expectation of success in concluding this fact because it was well known in the art that parathyroid adenomas result in primary hyperparathyroidism, as opposed to other causes, such as renal failure (see Cecil's, p.1402,para.4), known to cause secondary hyperparathyroidism.

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al. (U.S. Patent Application Publication No. 2002/0119202; Issued August 29, 2002, Filed August 9, 2001) in view of Altmann et al. ("Epothilones and Related Structures-A New Class of Microtubule Inhibitors with Potent In Vivo Antitumor Activity", *Biochimica et Biophysica Acta*, 1470 (2000):M79-M91) and further in view of Cecil's Textbook of Medicine (Twenty-First Edition, Vol.2; 2000; p.1402-1403).

Hunter et al. teaches anti-angiogenic compositions, as well as methods for utilizing such compositions for the treatment of cancer and other angiogenesis-dependent diseases, wherein the composition comprises (a) an anti-angiogenic factor and (b) a polymeric carrier (p.2, para.[0014]). Hunter et al. teaches that the anti-angiogenic factor that may be used include, *inter alia*, anti-invasive factor, retinoic acid and derivatives thereof, paclitaxel, suramin, etc. (p.7, para.[0100]), and further discloses that the anti-angiogenic compositions may additionally comprise compounds in addition to the anti-angiogenic factor and polymeric carrier, such as, *inter alia*, one or more compounds that disrupt microtubule function, e.g., epothilone (p.9, para.[0114]). Hunter et al. teaches that the disclosed anti-

angiogenic compositions may be employed in embolization therapy such that they are non-toxic, thrombogenic, easy to inject down vascular catheters, etc. (p.11, para.[0129]) for the treatment of benign tumors, including endocrine tumors, such as parathyroid adenomas (p.11, para.[0130]).

Note that, though Hunter et al. does not explicitly teach the treatment of recurrent or persistent parathyroid adenoma, the very teaching of "parathyroid adenoma" *per se* is understood to circumscribe both recurrent and persistent parathyroid adenoma, since recurrent or persistent adenoma provides for the two possible types of parathyroid adenoma that a subject suffering from said disease would have (i.e., persistent, in the sense that it does not resolve, or recurrent, in that it resolves and returns). This genus of possible types of parathyroid adenoma is sufficiently limited in size so as to place each member of the genus within the possession of the public.

Hunter et al. fails to teach (1) the use of the particular epothilone compounds of the instant claims (claims 10 and 12), (2) the particular dosing schedule (claim 13) or (3) the treatment of hypercalcemia resulting from parathyroid adenoma (claim 10).

Altmann et al. teaches epothilone compounds, such as those described in Fig.1 (i.e., epothilone A and epothilone B, which correspond to Applicant's instantly claimed epothilone structure of formula (I) wherein R is hydrogen for epothilone A or R is methyl for epothilone B; A is oxygen and R' is methyl; p.M80, col.1), that function as microtubule inhibitors with the ability to inhibit the growth of multi-drug resistant human cancer cell lines (p.M89, cols.1-2).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to employ any one of the epothilone compounds (e.g., epothilone A or B) in the anti-angiogenic composition disclosed by Hunter et al. as effective for the treatment of benign tumors, such as parathyroid adenoma, because Altmann et al. teaches that each of the disclosed epothilone compounds are one of a finite number of epothilone microtubule inhibitors known in the prior art at the time of the invention to predictably function as an anti-cancer agent. In other words, one of ordinary skill in the art at the time of

the invention would have found it *prima facie* obvious to employ any one of the known anti-cancer epothilone microtubule inhibitors (which, as evidenced by Altmann et al., includes, *inter alia*, epothilone A or B) into the formulation of Hunter et al. for use in treating parathyroid adenoma with a reasonable expectation of success because (1) a person with ordinary skill in the art has good reason to pursue known options within his or her technical grasp (i.e., in the instant case, known anti-cancer epothilone microtubule inhibitor agents) and (2) Hunter et al. teaches the desirability of including such a microtubule inhibitor into the disclosed anti-angiogenic composition for the treatment of cancers.

Regarding the instantly claimed dosage regimen (i.e., administering the epothilone weekly in a dose that is between about 0.1-6 mg/m^2 for three weeks after an interval of one to six weeks after the preceding treatment; claim 5), the determination of the optimal dosage regimen would have been a matter well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination and, if so, the identify and mechanism of action of the other drug such that any interactive effects may be taken into account. Thus, the dosage regimen and/or manner of administration that would have actually be employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Cecil's Textbook of Medicine teaches that primary hyperparathyroidism is a disorder in which hypercalcemia is due to hypersecretion of parathyroid hormone and is caused by solitary adenomas in about 85% of cases (p.1402).

In view of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the anti-angiogenic composition of Hunter et al. in view of Altmann et al. for the treatment of parathyroid adenoma *per se* would have been reasonably expected to exert the same or substantially equivalent efficacy in the treatment of hypercalcemia resulting from parathyroid adenoma because: (1) Hunter et al. teaches that an anti-angiogenic composition that may further comprise an epothilone microtubule inhibitor was known to have efficacy in treating patients with benign tumors, such as parathyroid adenomas *per se* and (2) Cecil's teaches that the majority of cases of parathyroid adenomas result in primary hyperthyroidism which causes hypercalcemia. In other words, Hunter et al. in view of Altmann et al. provides the clear teaching that the disclosed anti-angiogenic composition comprising an epothilone microtubule inhibitor is, in fact, effective for treating all parathyroid adenoma patients, i.e., 100% of patients with parathyroid adenoma, without exclusion. Of this entire population of parathyroid adenoma patients, Cecil's provides the factual extrinsic evidence demonstrating that a subpopulation of such parathyroid adenoma patients also suffer from hyperparathyroidism manifested as hypercalcemia. Accordingly, the suggestion of Hunter et al. in view of Altmann et al. to use the disclosed formulation for treating any parathyroid adenoma patient is a clear suggestion to use it in any subpopulation of parathyroid adenoma patients, such as those suffering from concomitant hypercalcemia, with the reasonable expectation of the same (or at least substantially equivalent) level of efficacy in treating these subpopulations of patients as would be expected in the treatment of parathyroid adenoma *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed compound has in treating the concomitant hypercalcemia must necessarily be present in the method disclosed by Hunter et al. in view of Altmann et al. and further in view of Cecil's, absent factual evidence to the contrary.

Conclusion

Rejection of claims 2-14 is proper.

Claims 15-16 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

November 19, 2009